Bard Electrophysiology
C.R. Bard, Inc.
55 Technology Drive
Lowell, MA 01851
(978) 441-6202
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K031000
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BARD

6. 510(k) SUMMARY FOR THE LabSystem III EP Laboratory

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990.

6.1 Submitter's Information

Name:	Bard Electrophysiology Division C.R. Bard, Inc.
Address:	55 Technology Drive Lowell, MA 01851
Phone:	(978) 323-2216 (Direct Line)
Fax:	(978) 323-2222
Contact Person:	Deborah L. Herrington Regulatory Affairs Manager
Date of Preparation:	March 28, 2003

6.2 Device Name:

Trade Name:	LabSystem III EP Laboratory
Common/Usual Name:	LabSystem
Classification Name:	Programmable Diagnostic Computer

6.3 Predicate Device Name(s):

The Coherent Systems, Inc.	- Coherent EP-STAT System* (K883152/October 13, 1988)
C.R. Bard, Inc.	- Bard BioPotential Amplifier (K874441/February 19, 1988)
C.R. Bard, Inc.	- Bard BioPotential Amplifier II - STAMP (K901358/November 27, 1991)
Bard Electrophysiology Division of C.R. Bard, Inc.	-High Level Input Isolation Module (K953267/February 27, 1996)

**Acquired by Bard in March 1989 and renamed the Bard LabSystem EP Laboratory and Bard LabSystem DUO EP Laboratory*

6.4 Device Description

The LabSystem III is a microprocessor based data acquisition system that is used during electrophysiology procedures to acquire ECG, intracardiac, pressure, and digital data from other devices like fluoro systems and RF generators. The ECG, intracardiac and pressure data are acquired by an amplifier that is connected to the patient via ECG leadwires and catheters. Although Bard Electrophysiology manufactures and distributes ECG leadwires and catheters, these devices are not included with the LabSystem III.

The amplifier filters and transmits the data to the computer where it is stored on optical disks and displayed on video monitors. The Bard LabSystem III EP Laboratory is available with a dual screen to provide the user with a review screen to analyze data and generate reports at the same time real-time data is being acquired. The real-time screen displays and records real-time data. This system allows the user to perform signal measurements and to print out waveforms.

The system is a software driven tool that acquires and displays data, stores and reports data. The system can also acquire and display data from other sources such as an RF generator. It does not transmit alarms or arrhythmias, nor does it have arrhythmia detection capabilities.

6.5 Intended Use of Device

The Bard LabSystem III* EP Laboratory is a computer and software driven data acquisition and analysis tool designed to facilitate the gathering, display, analysis by a physician, and storage of cardiac electrophysiologic data.

The Bard STAMP Amplifier is intended to amplify and condition electrocardiographic signals of biologic origin and pressure transducer input, transmitting this information to a host computer (the Bard LabSystem [III]* EP Laboratory) that can record and display the information.

* Please note that the name "LabSystem III" is a working name used for in-house development purposes. Also, the in-house temporary working name for the software is "Windows EP System" or "WEPS". A final name will be chosen prior to release of the Windows EP Software Version 1.0.

6.6 Summary of Technological Characteristics of the Bard LabSystem III EP Laboratory as Compared to the Predicate Device

Since 510(k) concurrence was received for the LabSystem and STAMP Amplifier, modifications have been made to the system. These modifications were made to enhance the amplifier module's manufacturability or user convenience and were deemed not to significantly alter the amplifier's overall safety and effectiveness and thus did not require new premarket notifications at the time the changes were made. Some of the changes were required for compliance with the ANSI/AAMI standard for Diagnostic Electrocardiographic Devices (EC11-1982, section 3.2.9).

- the ECG/Pressure module as described in K913875 has been upgraded to allow channel selection capability and the addition of notch filters for noise rejection;
- a 50/60 Hz notch filter was added to the module to filter the power line frequency and the input impedance of the module was increased from 1.6MegOhms to 10.6MegOhms;
- V-Lead/Pressure Plus module was configured to provide 6-lead channels only with the addition of notch filters and 2 pressure channels and the input impedance of the module was increased from 1.6MegOhms to 10.6MegOhms;
- the layout of the Intracardiac Pressure module was converted from through-hole components to surface mount components;
- the Stimulator Switch Plus module was upgraded to make its input sensitive to the 1.5V trigger inputs found on cardiac stimulators marketed in Europe; and
- various software enhancements for user interface ease of use.

These modifications are detailed in Section 2.2.

Like the LabSystem, various hardware and firmware upgrades have been made over the years to adapt to the ever-changing technology and to add user-preference features. Software changes have been implemented to address the changes in hardware/firmware. These modifications do not raise new issues of safety and effectiveness.

The technological characteristics of the LabSystem EP Laboratory and the LabSystem III EP Laboratory are essentially the same. Although changes to hardware/firmware and software have been made, the indications for use and the risks have not changed for this device. The system does not control the delivery of energy, it does not administer drugs, it does not perform any life-supporting or life-sustaining functions, it does not analyze data acquired during an EP procedure.

6.7 Discussion of Non-Clinical Tests and How the Results Support a Determination of Substantial Equivalence

The applicable standards pertaining to the software that drives the LabSystem III are listed below. These are the standards that were used for previous software versions and were used for Windows EP Software Version 1.0.

EN 60601-1-2: Ver 2:2001-9	Electrical Medical Device Standards
IEEE Standard 730-1995	Software Quality Assurance Plans
IEEE Standard 829-1983 (*1991)	Software Test Documentation
IEEE Standard 1012-1986 (*1992)	Software Verification & Validation Plans
IEEE Standard 830-1993	Software Requirement Specifications
IEEE Standard 1008-1987 (*1993)	Software Unit testing

*Reaffirmed by IEEE in year stated.

As previously stated, various modifications have been implemented with respect to the hardware, firmware and software that comprise the LabSystem. All equipment pertaining to the LabSystem is tested and certified to meet the following national and international safety standards.

EN60601-1-2: 2001-09	EMC, Radiated emissions & Conducted emissions requirements
EN60601-1:1990	Patient leakage current (section 19, Table IV, Type CF, 50uA

Software qualification is performed in-house on the system with results that meet acceptance criteria, thus confirming the safety and effectiveness of each functional aspect of the LabSystem III.

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The "510(k) Substantial Equivalence Decision-Making Process (Detailed)" decision tree (CDRH 510(k) Manual 92-4158) was utilized to make a determination of substantial equivalence. This decision tree is depicted in Section 4 in Figure 4-1 with the decision points relevant to the LabSystem III highlighted in yellow. The answers to the following questions at the indicated decision points in Figure 4-1 lead to a determination of substantial equivalence.

Provided in Section 4 is a document titled "Comparison of LabSystem Duo Capabilities and WEPS Capabilities". This document provides a comparison of the capabilities of the predicate device to the LabSystem III, subject of this 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 3 2003

Bard Electrophysiology
Division of C.R. Bard, Inc.
c/o Ms. Deborah L. Herrington
Regulatory Affairs Manager
55 Technology Drive
Lowell, MA 01851

Re: K031000
Trade Name: LabSystem III EP Laboratory with Windows Platform and EP Software Version 1.0
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: March 28, 2003
Received: March 31, 2003

Dear Ms. Herrington:

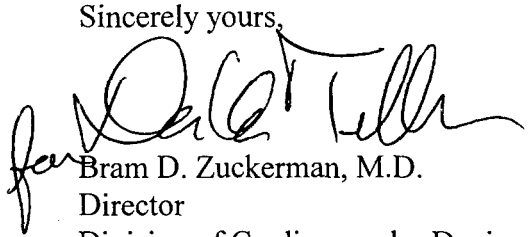
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K031000

1.5 INDICATIONS FOR USE

Device Name:

The Bard ***electro****physiology* LabSystem III* EP Laboratory

Indications for Use:

The Bard LabSystem III* EP Laboratory is a computer and software driven data acquisition and analysis tool designed to facilitate the gathering, display, analysis by a physician, pace mapping, and storage of cardiac electrophysiologic data.

The Bard STAMP Amplifier is intended to amplify and condition electrocardiographic signals of biologic origin and pressure transducer input, transmitting this information to a host computer (the Bard LabSystem [III]* EP Laboratory) that can record and display the information.

Contraindications:

None known.

* Please note that the name "LabSystem III" is a working name used for in-house development purposes. The in-house temporary working name for the software is "Windows EP System" or "WEPS". A final name will be chosen prior to release of the LabSystem III with Windows EP Software.

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K031000

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)